Data Provision Notice

Breast and Cosmetic Implant Registry (NHS providers)

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Background

The Health and Social Care Act 2012 (the Act) gives the Health and Social Care Information Centre, now known as NHS Digital and hereafter referred to by this name, statutory powers, under section 259(1), to require data from health or social care bodies, or organisations that provide health services or adult social care in England, where it has been directed to establish an information system by the Department of Health (DH) (on behalf of the Secretary of State) or NHS England.

The data, as specified by NHS Digital in this published Data Provision Notice, are required to support a Direction from DH to NHS Digital. Therefore, organisations that are in scope of the notice are **legally required**, under section 259(5) of the Act, to provide the data in the form and manner specified.

Purpose of the collection

NHS Digital has developed a Breast and Cosmetic Implant Registry (BCIR). This is expected to capture the details of all breast implant procedures completed in England by both the NHS and private providers. The Department of Health directed NHS Digital to carry out this work in response to Recommendation 21 of the Keogh Review of the Regulation of Cosmetic Interventions. See link: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192028/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf

The primary purpose of the BCIR is to record the details of any patient, who has had breast implant surgery, so that they can be traced in the event of a product recall or other safety concern relating to a specific type of implant. This is subject to explicit patient consent. Should an implant recall arise, an agreed process will be followed.

The secondary purpose of the BCIR is to provide an ‘early warning system’. A later phase of the registry is to introduce a facility to enter anonymised data, especially if consent rates prove to be low. This would then help provide a denominator for the total number of implant procedures, so if there was to be a recall in the future, the registry would indicate the full scale of the recall. More data on the registry would better inform an outlier process through the identification of any trends and complications related to specific implants.

NHS Digital may publish reports on the total numbers and types of implants, procedures and outcomes. These reports will only contain aggregated information (that is, data that has been grouped or combined) so that no individual patient will be identifiable.

Benefits of the collection

The main benefit of the BCIR is to improve patient safety by providing the ability to accurately track and trace patients in the event of a product recall following breast implant surgery in England. NHS Digital will not be able to trace overseas patients who consent to having their data stored. Furthermore, the BCIR can also be used to monitor outcomes which fall below an expected level, and report any such outliers to the Medicines and Healthcare Regulatory Agency (MHRA) and providers as necessary.

If for patient safety reasons, there is a need to contact patients and recall them for assessment, then details from the registry will be used by NHS Digital to attempt to trace the patients' current address using records held on the NHS Spine.

NHS Digital will then inform the relevant organisations that carried out the surgery, of the affected patients to be contacted, providing up-to-date address details where available, so that they can be advised of the appropriate steps to be taken to ensure their safety.

Legal basis for the collection, handling, publication and dissemination

NHS Digital has been directed by Department of Health under section 254 of the Health and Social Care Act 2012; to establish and operate a system for the collection and analysis of the information specified for this service. A copy of the Directions for the Breast and Cosmetic Implant Registry can be found here: https://www.gov.uk/government/organisations/health-and-social-care-information-centre/about/our-governance

This information is required by NHS Digital under section 259(1)(a) of the Health and Social Care Act 2012. In line with section 259(5) of the Act, all NHS providers performing breast and/or cosmetic surgery in England, must comply with the requirement and provide information to NHS Digital in the form, manner and period specified in this Data Provision Notice.

Explicit consent will be required from individual patients to add their patient details to the registry in addition to the usual consent for the surgical procedure. A patient information leaflet is to be made available to the patient before they sign the consent form, which has an opt in and opt out tick box. The patient information leaflet and consent form are available on the BCIR web page: http://digital.nhs.uk/bcir

The registry will be populated with records where a patient has consented. A Type 2 objection will not apply where the patient has explicitly consented to that disclosure.

This Notice is issued in accordance with the procedure published as part of NHS Digital duty under section 259(8).

This collection will be reviewed continuously post launch date and a formal review conducted by the end of March 2017, to assess the quality of the data entered and the consent model in place.

Persons consulted

Following receipt of a direction to establish a system to collect information on breast implant surgery, NHS Digital, as required under section 258 of the Health and Social Care Act 2012, set-up and consulted with the following persons who are members of the Breast and Cosmetic Implant Registry Steering Group which was set up by NHS Digital:

Organisation
Association of Breast Surgeons
Association of Independent Healthcare Organisations
British Association of Aesthetic Plastic Surgeons
British Association of Plastic, Reconstructive and Aesthetic Surgeons
Cosmetic Surgery Interspeciality Committee
Department of Health
East and North Hertfordshire NHS Trust
Healing Foundation National Institute of Aesthetic Research
Medicines and Healthcare Regulatory Agency
Patient representatives
Private Healthcare Information Network
Royal College of Surgeons
Royal College of Surgeons/Reconstructive Surgery Trials Network

Scope of the collection

Under section 259(1) of the Health and Social Care Act 2012, this Notice is served in accordance with the procedure published as part of the NHS Digital duty under section 259(8) on the following persons:

NHS Service Providers that provide specialist breast implant surgery including NHS funded and non-NHS funded patients.

Under section 259(5) of the Health and Social Care Act 2012, the organisation types specified in the above Scope must comply with the Form, Manner and Period requirements below:

Form of the collection

A list of the data items to be collected for the registry can be found in the document Data Collection Items and Paper Data Collection Form on the BCIR webpage: http://digital.nhs.uk/bcir

For certain data items, the NHS data dictionary has been referenced (e.g. gender).

The following patient identifiable information is included in the collection:

- NHS number (mandatory where available)
- First name (optional, mandatory if NHS number not provided)
- Surname (optional, mandatory if NHS number not provided)
- Gender (optional, mandatory if NHS number not provided)
- Date of birth (mandatory)
- Post code (optional, mandatory if NHS number not provided)

Manner of the collection

Data will be submitted by providers using the NHS Digital secure online Clinical Audit Platform (CAP).

A link to the system is available here: https://clinicalaudit.hscic.gov.uk/bir . Surgeons and administrative staff submitting data to CAP, will be required to register to use the system by creating a Single Sign On (SSO) account with NHS Digital and completing and submitting a Registration form which needs to be signed off by the designated Caldicott Guardian for the NHS Trust providing healthcare.

The registration process form can be found under User Documents on the right hand side of the BCIR webpage: http://digital.nhs.uk/bcir

An operational guidance note is also available under User Documents, on the right hand side of the webpage, to help providers submit data onto the registry: http://digital.nhs.uk/bcir

There is also a Paper Data Collection Form available under User Documents, for providers to record the required information, in the unlikely event of the CAP system not being available. It is suggested that data is captured electronically on CAP, as close to the point of care delivery as possible. Local processes should be agreed as to how the data collection is to be completed.

The dataset consists of patient confidential data items along with the name of the operating surgeon, details of the surgical procedure and details of the implant used. The full list of data items to be collected, can be found at: http://digital.nhs.uk/bcir

Period of the collection

The BCIR was launched on Monday 10th October 2016 and will be an ongoing collection. Providers will need to develop local processes as to when and how data is entered into the system but NHS Digital has advised in the support documents that it is best practice to submit the data as close to the surgery as possible.

NHS Digital has a statutory obligation to keep collections under review on an ongoing basis. As such, the BCIR is to be reviewed continuously post launch date and a formal review is to be carried out by end of March 2017 to ensure :

- That it remains fit for purpose
- To assess data quality
- That it maintains alignment with clinical safety
- That it is aligned to policy requirements
- That corrections are made in light of any errors highlighted by stakeholders.

A revised Data Provision Notice will be issued following any amendments to the dataset required for the registry as a result of any review.

Data Quality

The quality of the data being entered into the registry is to be reviewed continuously post launch date and a formal review conducted by the end of March 2017.

Any improvements needed to the system to aid data quality will be identified and actioned.

Providers will be informed of the need to improve the quality of the data entered and all supporting materials/documentation will be updated accordingly. This will continue to be reviewed until no further improvements are necessary.

Burden of the collection

Steps taken by NHS Digital to minimise the burden of collection

In discharging its statutory duty to seek to minimise the burden it imposes on others, NHS Digital has consulted on the data requirements of the registry with the BCIR Steering Group and identified what information is mandatory and non-mandatory. There has been detailed testing of the initial dataset by surgical teams, which has resulted in the dataset being reduced. It is recognised that there is no existing standard clinical system, recording all the required details. It is proposed that a file upload system will be developed to enable those that may have existing databases to upload data in place of manual data entry.

In seeking to minimise the burden it imposes on others, in line with sections 253 (2a) and 265(3) of the Health and Social Care Act 2012, NHS Digital has an assessment process to validate and challenge the level of burden incurred through introducing new information standards, collections and extractions.

This assessment is carried out by the Burden Advice and Assessment Service (BAAS) which carries out a Detailed Burden Assessment (DBA) and reports findings and recommendations, as part of the overarching Standardisation Committee for Care Information (SCCI) process. The Committee oversees the development, assurance and acceptance of information standards, data collections and data extractions for the health and social care system in England.

Detailed burden assessment findings

Recommendations to the collection owner included:

- Simplify the data registry to only include data essential to product recall.
- During revisions of the registry consideration should be given to the impact the registry's complexity has on compliance with requests for data.
- A follow up burden assessment to confirm burden figures within in the first six months and no later than April 2017.

  BAAS maintains and publishes a central register of assessed data collections and extractions, including burden assessment detail relating to all national collections. Further information about the collection and estimated costs can be viewed from this register.

Assessed costs

The associated burden of the data collection is:

Burden on providers	£379k	Includes all providers
Set up costs for the data collection	£83k	Includes NHS Digital and supplier costs, representing a maximum estimate.
Other costs of the data collection	£183k	Analysis and publication costs.

The provider costs are based on initial assessments carried out with a sample of providers by NHS Digital and grossed up to reflect the total cost for all providers.

Help us to identify inappropriate collections

NHS Digital's Burden Advice and Assessment Service (BAAS) offers a Collection Referral Service which is a simple and confidential way to allow data providers to refer data collections they feel would benefit from further scrutiny.

For more details and information on how to refer a collection, please visit:
http://www.digital.nhs.uk/article/6183/Collection-Referral-Service

More about the Burden Advice and Assessment Service can be found at:
http://digital.nhs.uk/baas

For further information

www.digital.nhs.uk

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